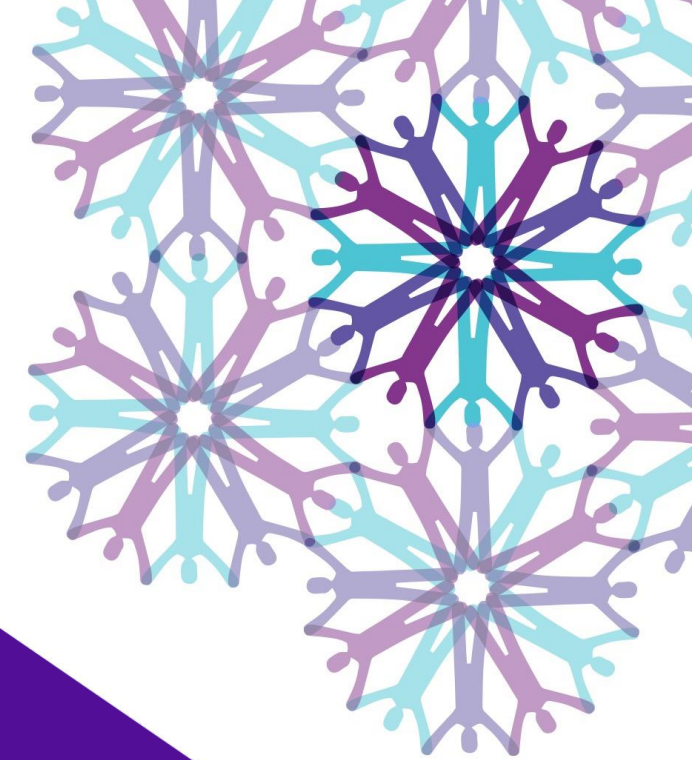


# CUSP2CT: Connecting Underrepresented Populations to Clinical Trials

Virtual Joint BSA-NCAB Board Meeting

CENTER TO REDUCE CANCER  
HEALTH DISPARITIES

LeeAnn Bailey, MBBS, PhD  
June 15, 2021



# CUSP2CT: A Timely Concept

## ENDING STRUCTURAL RACISM

### Ending Structural Racism

For NIH Staff  
For NIH Extramural Applicants and Awardees  
Health Equity Research  
Scientific Workforce Diversity  
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- NIH and NCI are united in efforts to end structural racism and racial inequities in biomedical research
- President Biden and Dr. Biden emphasized the importance of addressing cancer health disparities in R/E minority populations
- Outstanding need for outreach/education interventions to address key issues that affect diversity in research and especially in clinical trials
- CUSP2CT will advance an integrated and culturally appropriate approach to address key issues that affect diversity in clinical trials







# CUSP2CT Populations

## Underrepresented Populations:

Racial/ethnic minority populations  
(AA/Bs, AI/ANs, Asians, H/Ls,  
NH/OPIs)



# Minority Accrual to Clinical Trials (CTs) Has Improved: But Not Enough

Minority Accrual to NCI's NCTN and NCORP CTs (All Phases, %) and US Demographic data\*

R/E Minority Population	1999	2019	U.S. Population Demographics- 2019
Black or African American	8%	11%	13.4%
Hispanic or Latino	4%	10%	18.5%
Asian	2%	4%	5.9%
American Indian and Alaskan Native	0.3%	0.5%	1.3%
Native Hawaiian and Other Pacific Islander	0.2%	0.3%	0.2%
More than One Race	0.1%	0.6%	2.8%
<b>Total</b>	<b>14.6%</b>	<b>26.4%</b>	<b>42.1%</b>

## Phase 3 Accrual data for FY 2019 and FY 2019

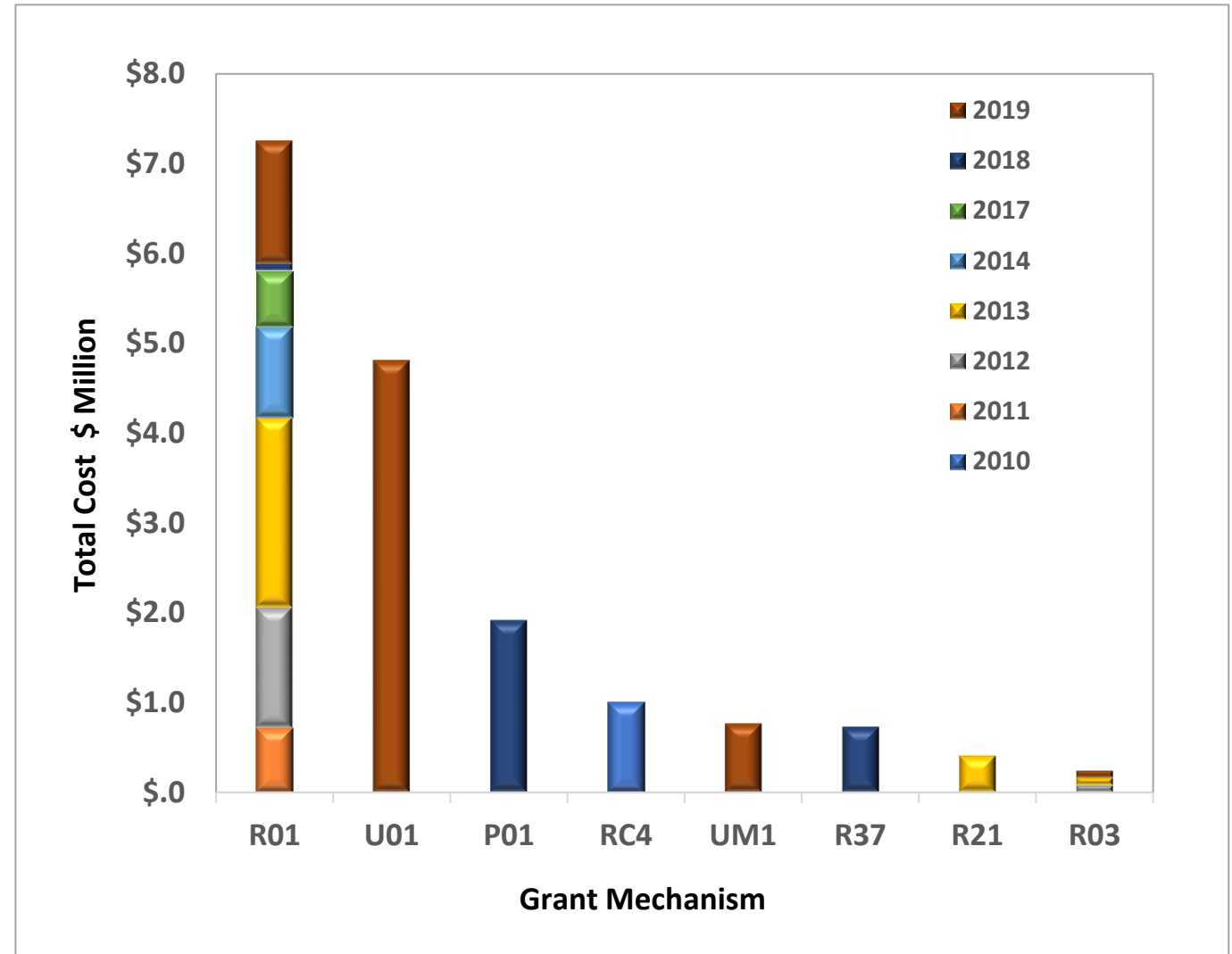
	1999	2019
Accrual of Minority Patients to Phase III Trials	14%	27%

\*Sources: Dr. Wortia McCaskill-Stevens, BSA/NCAB, June 15, 2020  
U.S. Census Bureau, QuickFacts- Race and Hispanic Origin, July 1, 2019



# Portfolio Analysis

- Portfolio analysis of NCI-funded grants focused on clinical trials (CTs) and underrepresented populations
- 24 grants totaling cost of \$17.1M, mostly R01 mechanism (\$7.2M)
- NCORP and NCTN sites prominent, as well as the Minority-Based NCORP Program
- While many of these grants were focused on underrepresented populations and clinical trials, there remains a gap within the NCI portfolio on studies that integrate best practices and establishing connections within the community



# CUSP2CT: Enhancing Existing NCI CT Programs

## National Clinical Trial Network (NCTN)

Coordinates and supports cancer clinical trials at more than 2,200 sites

## NCI's Community Oncology Research Program (NCORP)

CT conduction and care delivery:  
7 Research Bases and 46 Comm Sites & 14 minority sites

## Experimental Therapeutics Clinical Trials Network (ETCTN)

Conducting early-stage trials of cancer treatment therapies

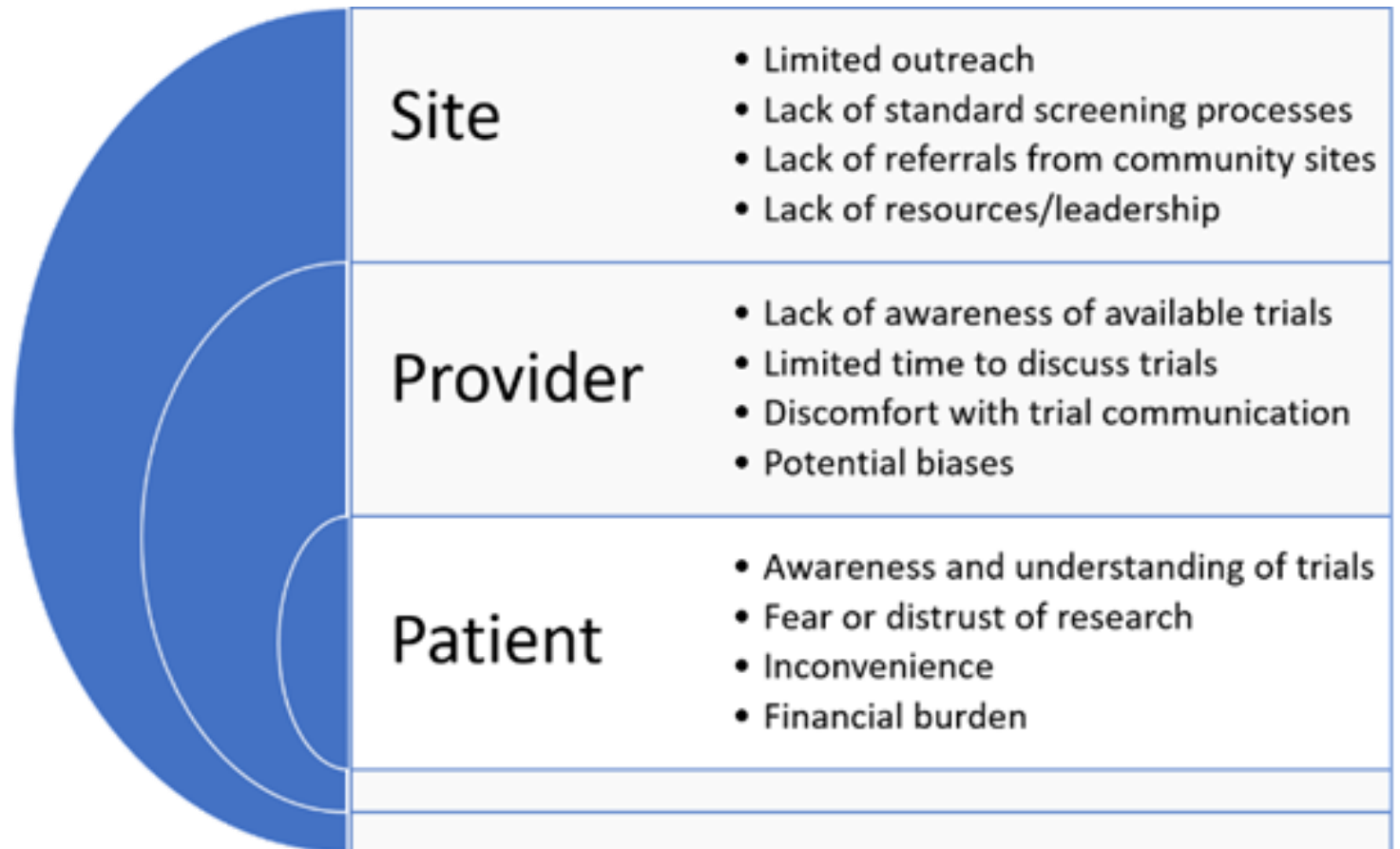
## Community Outreach and Engagement (COE)

Embedded within CCs, addresses cancer concerns in respective catchment areas

**CUSP2CT:** Enhances CT participation among R/E minority populations through a partnership of Community Health Educators (CHEs)/ Lay Health Advisors (LHAs), CT Coordinators (CTCs), and referring providers (PCPs and Oncologists)

# Multilevel Barriers to CT Referral of R/E Minority Patients

- There are multiple barriers at different levels that keep R/E patients from being referred to CTs
- It is necessary to address barriers at all levels to impact referral, and future recruitment into CTs using an integrated team approach



# Referral Challenges in R/E Minority Populations

- Lack of information about available CTs
- Long-standing fear, apprehension, and skepticism
- Doctors may not mention clinical trials as an option for cancer care
- Different cultural values and beliefs that may be different than principles of Western medicine
- Language or literacy barriers
- Additional access problems: time, distance, and costs

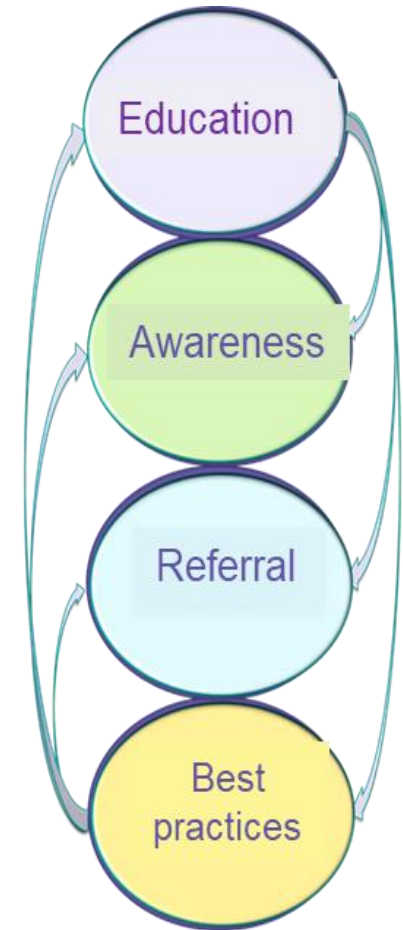
*If R/E minority populations are not engaged and educated about CTs, they will not participate in CTs!*



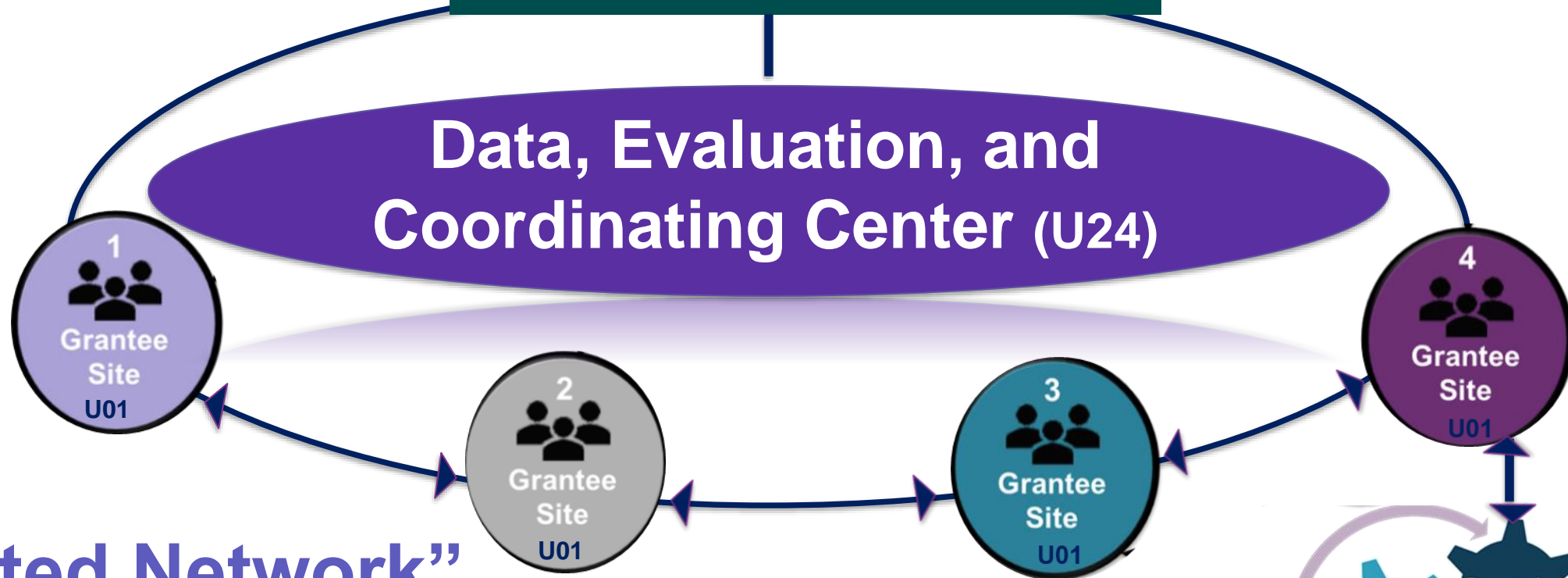
# CUSP2CT Purpose and Objectives

**Purpose:** *To implement and evaluate multi-level and culturally tailored outreach and education interventions with the primary goal to increase referral of racial/ethnic (R/E) minority populations to NCI-supported clinical trials.*

- **Educate** R/E minority populations about NCI-supported clinical trials utilizing LHAs, CHEs, in the integrated team
- Engage primary care and referring providers to **increase clinical trial awareness** to refer R/E minority populations to NCI-supported clinical trials utilizing LHAs, CHEs, in the integrated team
- Enhance **referral of R/E minority populations to NCI-supported clinical trials** at the site, provider, and patient levels utilizing LHAs, CHEs, in the integrated team
- Address **barriers** and **facilitators** that impede and support **pathways** by which R/E minority populations access NCI-supported clinical trials at the site, provider, and patient levels. Identify and disseminate best practices



# CUSP2CT Network



## “Integrated Network”

The **CUSP2CT Network** is composed of a Data, Evaluation, and Coordinating Center (DECC), which connects and coordinates the grantee sites (U01).

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# Program Expectations of each Grantee Site (U01)

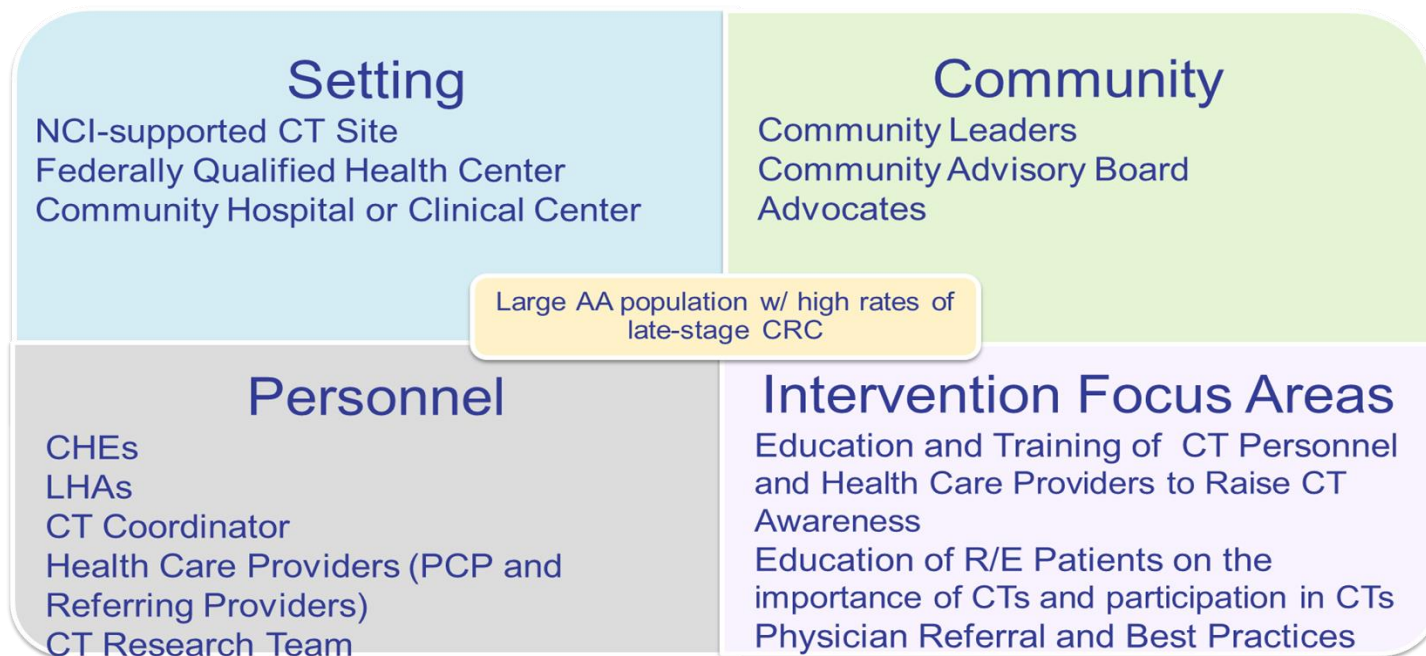
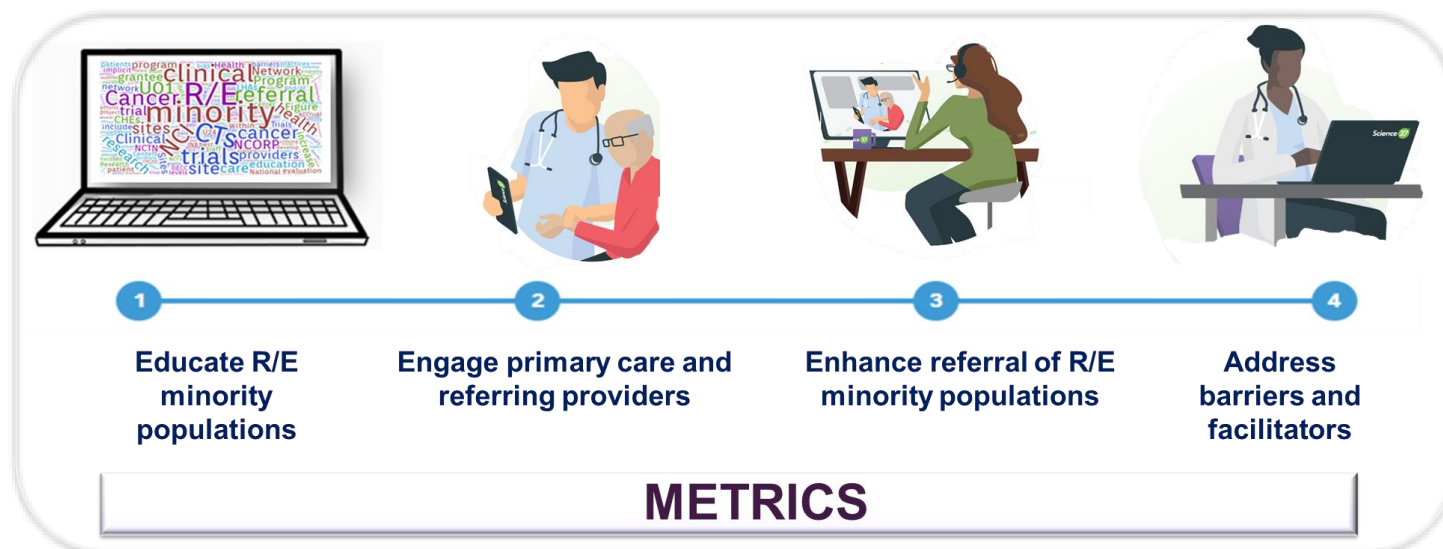
- Leverage existing partnerships and foster new partnerships with community-based organizations to collaborate in tandem with CHEs/LHAs
- Leverage existing partnerships and foster new partnerships with referring providers to enhance the identification of potential R/E minority referrals to CTs
- Identify available and appropriate CTs that have a strong potential for positively impacting cancer health disparities
- Establish baseline data regarding community members awareness and knowledge of CTs as well as referring providers' referral of R/E minority patients to CTs
- Implement, and evaluate novel multilevel interventions to enhance (R/E) diversity in NCI-supported (CTs)





# Elements of a Competitive Application

- Cancer Type and Target Population
- Integrated Site Team
- Community Intervention
- Provider Intervention
- Referral System
- Identification of Best Practices



# Data, Evaluation, and Coordinating Center (U24)

- Receive, store, and analyze data from the U01 grantee sites
- Identify and/or develop common metrics and measures to be collected by all U01 grantee sites to facilitate a CUSP2CT program evaluation
- Assist sites in evaluating their specific interventions and making changes as appropriate at the patient, provider, and site levels
- Develop an overall program evaluation plan and conduct an evaluation of the CUSP2CT network
- Disseminate results for all implemented interventions within and outside of the CUSP2CT network, with sufficient detail to allow non-grantee sites to replicate the evaluated interventions
- Encourage the replication and scale up of effective interventions and best practices

# CUSP2CT Select Evaluation Metrics for Objectives

Objectives	Metrics	Data Sources
<b>1. Educate R/E minority populations</b>	<ul style="list-style-type: none"><li>• Number and types of CT-related outreach and education activities conducted with R/E minority community members, and number of persons reached.</li><li>• Demonstrated knowledge of CTs in persons from R/E minority Populations, at pre- and post-education activity.</li></ul>	<ul style="list-style-type: none"><li>• CHE and LHA logs/reports; key informant interviews</li><li>• Focus Groups/Surveys</li></ul>
<b>2. Engage primary care and referring providers</b>	<ul style="list-style-type: none"><li>• Number and types of activities designed to educate primary care and referral providers about NCI-supported clinical trials</li><li>• Health care providers' knowledge and awareness of implicit bias</li></ul>	<ul style="list-style-type: none"><li>• Clinic and CT data</li><li>• Provider surveys and focus groups</li></ul>
<b>3. Enhance referral</b>	<ul style="list-style-type: none"><li>• Number of referrals to NCI-supported clinical trials, by trial type (e.g., prevention, screening, treatment)</li><li>• Number of provider referrals of R/E minority populations to NCI-supported clinical trials</li><li>• Tracking successful accruals</li></ul>	<ul style="list-style-type: none"><li>• EMR/EHR</li><li>• Referral logs</li><li>• Accrual logs</li></ul>
<b>4. Address barriers and facilitators that impede and support pathways</b>	<ul style="list-style-type: none"><li>• Identification and clear description of pathway(s) to access CTs (i.e., a "roadmap")</li><li>• Identification of best practices</li></ul>	<ul style="list-style-type: none"><li>• CHE/LHA logs/reports</li><li>• Cross-site comparisons of activities/processes</li></ul>

# Budget

Funding Mechanism	1 Year				5 Years			
	1 Site		4 Sites		1 Site		4 Sites	
	DC	TC	DC	TC	DC	TC	DC	TC
U01	\$450 K	\$765 K	\$1.80 M	\$3.06 M	\$2.25 M	\$3.83 M	\$9.00 M	\$15.30 M
U24	\$350 K	\$595 K			\$1.75 M	\$2.98 M		

Funding for CUSP2CT (U01 and U24 at for 1- and 5-year periods). TC assumes 70% F&A cost/per year.

- Up to four (4) U01 Grantee Sites will be awarded. The project period is for 5-years, with \$450K direct costs (\$765K total costs)/award/year. The budget will encompass Fiscal Years 2022-2026.
- One (1) U24 grant will be awarded. The project period is for 5-years, with \$350K direct costs (\$595K total costs)/year.

**The estimated total costs per year are \$3.67 M. The estimated total costs for the five-year project period are \$18.28M.**



# Key Aspects of CUSP2CT

- Use of an integrated network to address several levels of challenges to CT referral, enrollment and retention
- Increased community engagement education, awareness, and CT referral through CHEs/LHAs
- Implement and adapt innovative strategies for CT participation of R/E minority populations
- Leverage existing programs/research



# CUSP2CT Key Contributors

- **Office of Cancer Centers: Sonya Roberson**
- **Office of Cancer Clinical Proteomics Research: Christopher Kinsinger**
- **Division of Cancer Control and Population Sciences: Ann Geiger, David Chambers, Antoinette Percy-Laurry**
- **Division of Cancer Treatment and Diagnosis: Grace Mishkin, Andrea Denicoff, Meg Mooney**
- **Division of Cancer Prevention: Wortia McCaskill-Stevens, Jennifer Pak, Diane St. Germaine, Alexis Bakos**
- **Division of Cancer Biology: Phil Dashner**
- **National Human Genome Research Institute: Carla Easter**
- **National Institute of Mental Health: Diana Morales**
- **National Institute on Minority Health and Health Disparities: Adelaida Rosario**
- **Equity Council ERAD Work Group and Tiffany Wallace**
- **Center to Reduce Cancer Health Disparities CUSP2CT Team: Sandra San Miguel, Sheba Dunston, Anil Wali, Liz Perruccio, Fred Snyder, and Jay Revilleza**

# Thank you!



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